

111TH CONGRESS
2^D SESSION

S. 1674

AN ACT

To provide for an exclusion under the Supplemental Security Income program and the Medicaid program for compensation provided to individuals who participate in clinical trials for rare diseases or conditions.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Improving Access to
3 Clinical Trials Act of 2009”.

4 **SEC. 2. FINDINGS.**

5 Congress finds the following:

6 (1) Advances in medicine depend on clinical
7 trial research conducted at public and private re-
8 search institutions across the United States.

9 (2) The challenges associated with enrolling
10 participants in clinical research studies are especially
11 difficult for studies that evaluate treatments for rare
12 diseases and conditions (defined by the Orphan
13 Drug Act as a disease or condition affecting fewer
14 than 200,000 Americans), where the available num-
15 ber of willing and able research participants may be
16 very small.

17 (3) In accordance with ethical standards estab-
18 lished by the National Institutes of Health, sponsors
19 of clinical research may provide payments to trial
20 participants for out-of-pocket costs associated with
21 trial enrollment and for the time and commitment
22 demanded by those who participate in a study. When
23 offering compensation, clinical trial sponsors are re-
24 quired to provide such payments to all participants.

25 (4) The offer of payment for research participa-
26 tion may pose a barrier to trial enrollment when

such payments threaten the eligibility of clinical trial participants for Supplemental Security Income and Medicaid benefits.

(5) With a small number of potential trial participants and the possible loss of Supplemental Security Income and Medicaid benefits for many who wish to participate, clinical trial research for rare diseases and conditions becomes exceptionally difficult and may hinder research on new treatments and potential cures for these rare diseases and conditions.

SEC. 3. EXCLUSION FOR COMPENSATION FOR PARTICIPATION IN CLINICAL TRIALS FOR RARE DISEASES OR CONDITIONS.

(a) EXCLUSION FROM INCOME.—Section 1612(b) of the Social Security Act (42 U.S.C. 1382a(b)) is amended—

(1) by striking “and” at the end of paragraph (24);

(2) by striking the period at the end of paragraph (25) and inserting “; and”; and

(3) by adding at the end the following:

“(26) the first \$2,000 received during a calendar year by such individual (or such spouse) as compensation for participation in a clinical trial in-

volving research and testing of treatments for a rare disease or condition (as defined in section 5(b)(2) of the Orphan Drug Act), but only if the clinical trial—

“(A) has been reviewed and approved by an institutional review board that is established—

“(i) to protect the rights and welfare of human subjects participating in scientific research; and

“(ii) in accord with the requirements under part 46 of title 45, Code of Federal Regulations; and

“(B) meets the standards for protection of human subjects as provided under part 46 of title 45, Code of Federal Regulations.”.

(b) EXCLUSION FROM RESOURCES.—Section 1613(a) of the Social Security Act (42 U.S.C. 1382b(a)) is amended—

(1) by striking “and” at the end of paragraph (15);

(2) by striking the period at the end of paragraph (16) and inserting “; and”; and

(3) by inserting after paragraph (16) the following:

“(17) any amount received by such individual (or such spouse) which is excluded from income under section 1612(b)(26) (relating to compensation for participation in a clinical trial involving research and testing of treatments for a rare disease or condition).”.

(c) MEDICAID EXCLUSION.—

(1) IN GENERAL.—Section 1902(e) of the Social Security Act (42 U.S.C. 1396a(e)), is amended by adding at the end the following:

“(14) EXCLUSION OF COMPENSATION FOR PARTICIPATION IN A CLINICAL TRIAL FOR TESTING OF TREATMENTS FOR A RARE DISEASE OR CONDITION.—The first \$2,000 received by an individual (who has attained 19 years of age) as compensation for participation in a clinical trial meeting the requirements of section 1612(b)(26) shall be disregarded for purposes of determining the income eligibility of such individual for medical assistance under the State plan or any waiver of such plan.”.

(2) CONFORMING AMENDMENT.—Section 1902(a)(17) of such Act (42 U.S.C. 1396a(a)(17)) is amended by inserting “(e)(14),” before “(l)(3)”.

1 (d) EFFECTIVE DATE.—The amendments made by
 2 this section shall take effect on the date that is the earlier
 3 of—

4 (1) the effective date of final regulations pro-
 5 mulgated by the Commissioner of Social Security to
 6 carry out this section and such amendments; or

7 (2) 180 days after the date of enactment of this
 8 Act.

9 (e) SUNSET PROVISION.—This Act and the amend-
 10 ments made by this Act are repealed on the date that is
 11 5 years after the date of the enactment of this Act.

12 **SEC. 4. STUDY AND REPORT.**

13 (a) STUDY.—Not later than 36 months after the ef-
 14 fective date of this Act, the Comptroller General of the
 15 United States shall conduct a study to evaluate the impact
 16 of this Act on enrollment of individuals who receive Sup-
 17 plemental Security Income benefits under title XVI of the
 18 Social Security Act (referred to in this section as “SSI
 19 beneficiaries”) in clinical trials for rare diseases or condi-
 20 tions. Such study shall include an analysis of the following:

21 (1) The percentage of enrollees in clinical trials
 22 for rare diseases or conditions who were SSI bene-
 23 ficiaries during the 3-year period prior to the effec-
 24 tive date of this Act as compared to such percentage

1 during the 3-year period after the effective date of
2 this Act.

3 (2) The range and average amount of com-
4 pensation provided to SSI beneficiaries who partici-
5 pated in clinical trials for rare diseases or condi-
6 tions.

7 (3) The overall ability of SSI beneficiaries to
8 participate in clinical trials.

9 (4) Any additional related matters that the
10 Comptroller General determines appropriate.

11 (b) REPORT.—Not later than 12 months after com-
12 pletion of the study conducted under subsection (a), the
13 Comptroller General shall submit to Congress a report
14 containing the results of such study, together with rec-
15 ommendations for such legislation and administrative ac-
16 tion as the Comptroller General determines appropriate.

Passed the Senate August 5, 2010.

Attest:

Secretary.

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